Processed Apples Institute

March 4, 2003

Mr. Stuart Shapiro
Desk Officer for the Food and Drug Administration
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building
725 17th Street, NW
Room 10235
Washington, DC 20503

RE: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
Docket No. 02N-0278

Dear Mr. Shapiro:

The Processed Apples Institute (PAI) is a trade association composed of companies producing apple products: juices, sauces, flavors, essences, etc. Our members produce a major portion of the apple juice and applesauce manufactured annually in the United States. PAI submits the following comments on the cost estimates outlined in Section IV of the Food and Drug Administration's proposed regulation: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which was published in the February 3, 2003, *Federal Register* (68 FR 5428).

Section IV. A. 4.

As stated in Section IV, once the U.S. importer or U.S. purchaser of the food becomes aware of the regulation, he or she would need to find a copy of the prior notice requirements, read the requirements and understand them. The FDA estimates that it takes responsible parties with Internet access one hour to research the prior notice requirements. Table 1 of Section IV shows a first year one-time research cost of $1,865,683 for firms with Internet access. The cost is calculated based on one hour of research time by the administrative worker at a rate of $25.10 and multiplied by 74,330 firms with Internet access.

PAI believes this cost is significantly underestimated and does not take into account the time required to read and understand the prior notice regulation. It may take the administrative worker one-hour to find the document using the Internet, but more time would be required to effectively implement the regulation. The administrative worker would probably not be the person reviewing the document for content or formulating a plan for implementation. This would likely be the responsibility of the firm's manager or in some instances, the company's legal counsel. If we estimate this process takes 10 hours of a manager's time at a rate of $56.74, this would increase the research cost for a firm with Internet access to 567.40 per

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firm. The research cost of each firm with Internet access would be increased to $592.50 (i.e., 1 hour of time for the administrative worker and 10 hours of time for the manager). Firms that do not have Internet access would incur similar costs, except the time for the administrative worker to research the regulation is two hours instead of one.

Using the information in option 2, Table 1, this would change the total first year one-time research costs for all importing firms with the Internet to $44,040,525 as opposed to the proposed cost of $1,865,683. The total first year one-time research costs for all firms without the Internet would be $1,912,707 instead of the proposed cost of $155,469.

If a firm uses legal counsel to assist with the regulation, this would increase the expense for implementation even more. For example, if it took legal counsel five hours to review the regulation at a cost of $300 per hour, the cost estimate would increase by $1,500.

Table 3 of Section IV shows the total cost per import entry as $33.02. This cost is based on one hour of time - 45 minutes of an administrative worker's time at $25.10 and 15 minutes of a manager's time at a rate of $56.74. This includes an administrative worker's time to gather and input the data and time for the manager to review the prior notice screen. PAI believes that it would take more than one hour for the information to be gathered and put into the prior notice screen. We believe the time could easily be doubled to 120 minutes. Some of the required information for the prior notice submission may be readily available to the administrative assistant (e.g., information on the submitting firm, entry type, product identity, manufacturer, importer, owner and consignee). The administrative worker may need to obtain information, such as product lot numbers, production codes, grower information, and anticipated arrival information. The required FDA registration numbers for the manufacturer, shipper, importer, owner and consignees may not be known initially. The process of gathering the information for submission would require communication between various parties at considerable extra cost.

We appreciate your consideration of these comments.

Sincerely,

Andrew E. Ebert

Andrew G. Ebert
President